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Bioprospecting in the High Seas: Regulatory Options for Benefit Sharing

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Judging from the debates on the international political scene, the legal regime for the marine areas beyond national jurisdiction might be changing in the years to come. One recurring question is whether and how future international law should incorporate the issue of sharing the benefits that arise from utilizing marine genetic resources (MGRs). In reviewing these questions, this work outlines some of the regulatory options for addressing the activity of bioprospecting in the high seas. *De lege ferendae* the activity of bioprospecting will likely give rise to a wide range of legislative alternative forms of benefit sharing. These must be consistent with the fundamental principle of freedom of the high seas and the exclusive rights awarded by patents when the activity results in an invention; yet they should also have advantages in terms of conserving MGRs, promoting fairness and spurring innovation. When emphasis is placed on maintaining the incentives to innovate, there are important drawbacks to monetary benefit sharing. On the other hand, open or semi-open source options can be conceived for the material relating to MGRs. This article identifies important practical implications and unresolved legal and practical questions for owners of sampled material and for third-party users.

Keywords access and benefit sharing; bioprospecting; high seas; marine genetic resources

Introduction

Bioprospecting, the search for new and useful biological and genetic resources, is taking place in the high seas. These expeditions, often referred to as "cruises", fulfil a range of different purposes, from pure academic, taxonomic mapping of species occurrence, to commercially oriented exploitation of marine genetic resources (MGR). Despite this activity, knowledge of marine life, species and genetic resources is still limited. The current and future legal status of MGR and bioprospecting in areas beyond national jurisdiction (ABNJ) has been the subject of debate for several years, though discussions have yet to provide answers that inspire consensus. Furthering these discussions necessitates exploring the points of intersection of several regimes of international law. The use of the high seas is governed by the law of the sea, as reflected in the United Nations Convention on the Law of the Sea (UNCLOS).[1] Patent law provides a system for establishing exclusive rights to inventions, including to those based on biological material, regardless of where the material was found (Tvedt, 2010). The rationale for sharing benefits that arise from MGR comes *inter alia* from the Convention on Biological Diversity (CBD)[2] and its Nagoya Protocol (NP),[3] which does not directly apply to ABNJ, apart from what flag state legislation may warrant. The balance between patents and other rights to genetic resources that the CBD seeks to establish through Access and Benefit Sharing (ABS) is absent for ocean resources. Free and open access, combined with applicability of exclusive rights through the patent system, prompts the question of whether there is need for a feedback mechanism also in the case of genetic resources in the high seas.

Sharing of benefits from the utilization of MGR remains a controversial topic. In this article, we explore two main proposals for benefit sharing from bioprospecting for marine resources in the high seas: monetary sharing from utilization of MGRs and sharing of genetic material itself. Subsequently, we

discuss institutional options for benefit sharing for the high seas. As the MGR in the Area[4] have generated more overt debate and a more substantial body of literature[5] than those in the high seas, this article focuses on the particularities of the high seas. Before analysing concrete alternatives for the roads ahead, we will first briefly introduce the state of discussions on a possible future regulation of MGR in ABNJ, and second, develop criteria for assessing the two proposals.

State of the Discussions on MGRs in ABNJ

The main forum in which the question of possible benefit sharing from the utilization of high seas MGR is the Ad Hoc Open-ended Informal Working Group to study issues relating the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction (hereinafter the Working Group), established by the United Nations General Assembly.[6] Present in meetings of the Working Group are chiefly representatives of states, but also intergovernmental organizations and non-governmental organizations. The mandate of the Working Group includes indicating options "to promote cooperation and coordination for the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction".[7] Some see in the mere establishment of the discussion forum an evident preparing of ground for regimes that regulate the exploitation of genetic resources in ABNJ (Treves, 2010, p. 17).

As common ground, delegations value the conservation of MGR and the importance of scientific research.[8] Concerning the exploitation of MGR, the only consensus so far seems to be the need to improve knowledge on existing activities, their costs and implications for the marine environment (Broggiato, 2011, p. 185). While several parties to UNCLOS are eager to move the debate further, the discussions testify to the long-lasting impasse between partisans and objectors to the idea of defining MGRs in ABNJ as "common heritage of mankind".[9] As an alternative option, the EU suggested in 2008 taking the multilateral mechanism under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[10] as a reference point for the discussions.[11] Though most parties welcomed the proposal (Broggiato, 2008, p. 186), it has so far not lead to concrete proposals in subsequent meetings.

Despite the lack of concrete text proposals, delegates to Rio + 20 took only a few weeks after the 2012 meeting of the Working Group, note of the work of the group and committed "on an urgent basis" to address the issues of conservation and sustainable use of marine biodiversity in ABNJ, "including by taking a decision on the development of an international instrument under the United Nations Convention on the Law of the Sea".[12] Even if parties agree that MGR are common heritage of mankind, this does not necessarily provide clear guidance on how a benefit-sharing scheme shall be construed. For as Leary explains, that regime is tailored for mineral resource exploitation and does not answer how benefit sharing would be done when inventions are patent protected (Leary, 2009, p. 366). Also when plant genetic resources were recognized as common heritage (before the 1980s) no system for benefit sharing from utilization of these resources was in place. In this situation, proposals on benefit-sharing options often take a quite general form. It is therefore all the more important that the academic discussion strives towards fleshing out concrete possibilities.

Criteria for Outlining and Evaluating Regulatory Options

In this article, we aim to contribute to the ongoing discussions by exploring two regulatory options for bioprospecting in the high seas. These two policy options will be evaluated on their capacity to spur innovation, promote conservation and ensure sustainable use of marine biodiversity, and whether a policy presents a fair option.

A first criterion is that of the potential of a regulation to *spur innovation*. This includes basic academic and scientific innovation that furthers knowledge of the ocean, and the commercial development of

applications of biological diversity that lead to new products available on the market. A major source of scepticism towards ABS in general, voiced by certain developed states, is that regulation will put an unnecessary strain on the creators of innovation, that is industry and businesses, thus constituting a disincentive to innovate.[13] Though not a new argument, it should be seen in relation to the economic downturn of recent years.[14] In an industry where R&D is the fundamental ingredient of the innovation wanted by all parties, avoiding unnecessary strain on the creators of innovation is paramount. Often the availability of intellectual property rights (IPR) protection, as patents, is considered important. Therefore, any proposed scheme must correlate positively with innovation and be aware of any links to IPR and patents in particular.

Conservation, a second criterion, is here understood as both *in situ* and *ex situ* conservation of biodiversity. As defined in CBD article 2, *in situ* conservation is "the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings […]".[15] *Ex situ* conservation is the "conservation of components of biological diversity outside their natural habitats".[16] An example of *ex situ* conservation is keeping reproductive material in collections as a resource for research, or for reintroduction of endangered species into the wild. It should be reiterated here that CBD does not apply to ABNJ,[17] and it is not obvious that the definitions of this Convention would prevail in a setting relating to the law of the sea. Conservation of marine biodiversity *ex situ* is second best to maintaining biodiversity *in situ*. *Ex situ* conservation is connected to spurring innovation insofar as marine material in a collection will be more accessible as the raw material for innovation compared to the innovator having to search for it in wild. The collections of plant genetic resources have been crucial in plant breeding; keeping collections of marine material could have a similar potential.

Sustainable use, as a sub-notion of sustainable development,[18] reflects two key concepts, that of a present and future need; and that "of limitations imposed by the state of technology and social organization on the environment's ability to meet present and future needs".[19] Here the resources used are MGR and therefore the question is how well policy proposals reflect their sustainable use.

Fairness is often taken to refer to general conceptions of what is just and morally right. On an international level, the concept of fairness often refers to the general North–South gap in development and that between the bioprospector and the involuntary bystander.[20] Despite different existing notions of fairness, the discussions here are inspired by a Rawlsian perspective, as described in *A Theory of Justice* (Rawls, 1999). The essence of this conception of fairness is that any new legal tool must contribute at least so that the worse off be put in a slightly better position. Although Rawls did not himself apply his theory to international issues without modification (Rawls, 1993, pp. 36–68, 1999, pp. 331–5), his ideas can inspire the discussion on marine bioprospecting. With respect to marine biological material, fairness could play an even greater part than in the CBD, under which the sharing the benefits that arise from utilization of GR ideally entails a return of said benefits to a national or local entity in a provider country, thus creating an incentive to safeguard and conserve biodiversity.[21] Since there is no providing or conserving party in the high seas, it can be argued that, compared to the situation under the CBD, ABS for the high seas could fulfil a function that is more redistributive of means and know-how, than conservationist.

We set out as the task of this article to examine two legal proposals in the light of these four criteria: potential for new innovation, conservation, sustainable use and fairness.

First Policy Option: A Global Multilateral Benefit-Sharing Fund

This section examines one possible modality for ABS for the high seas, namely monetary benefit sharing. Since there are no sovereign rights of states to MGR in the high seas as is the basis for benefit sharing under the CBD, it is most relevant to discuss a global system for sharing benefits. If a mechanism is multilateral, it could take the form of a fund that serves as focal point and administers the monetary transactions.

In a scenario where money is to be transferred to a fund to be shared later, one question is whether contributions from bioprospectors or subsequent product developers should be mandatory or voluntary. If voluntary, contributions to the fund would depend on the incentives of bioprospectors, industry and other possible contributors. The possibility of making voluntary contributions would not affect the economical assessments of a company considering engaging in bioprospecting; it would thus not inhibit innovation in any way. On the other hand, there is a risk that a fund would simply not be used, and that there would be only symbolic funds available for the promotion of fairness, innovation, conservation or sustainable use. It is not easy to imagine what incentives could be envisaged that would make a company or a university contribute to such a fund.

If contributions are mandatory, an obligation has to be triggered at a specific point, be it during bioprospecting or at any subsequent stage in research or commercialization. When identifying trigger points, parallel questions to implementation of ABS in the CBD arise.[22] It must, for example, take heed of the widespread discussion about distinguishing academic research from commercial purposes. For the sake of promoting innovation, these triggers would have to be set in a legally predictable and objectively determined manner, so that investors and bioprospectors could have a good basis for making a decision on exploitation of MGR (Young and Tvedt, 2009, p. 115).

One such trigger could be the initial moment at which any legal or natural person has established a wish to conduct a cruise. The question is what the implications would be of choosing this early trigger. At that point in time, different bioprospectors will have different intentions, not to mention that different actors might participate on board the same ship conducting a cruise. If the aim is to make obligations fall only on commercially oriented bioprospecting, by exempting academic cruises from the scope of benefit-sharing requirements, this trigger might incentivise commercial cruises to sail under an academic flag. Such an early trigger could end up not generating much monetary benefits for the promotion of conservation, sustainable use and fairness.

The time lag between conducting a commercial bioprospecting cruise and achieving commercial success can be long. To put a monetary obligation on the event of the cruise as the trigger point could reduce the incentive to innovate. If the aim is to make no distinction of pure and applied sciences, it should be noted that no commercial benefits have been created at this moment. Especially if the obligation takes the form of monetary benefits, this trigger can be perceived as a tax placed on an intention to pursue research. Opting for a trigger point closer to actual commercialization would likely be more conducive to promoting a fair system that encourages innovation.

In the discussions leading up to the establishing of the NP under the CBD, an expert group suggested a list of specific categories of utilizations and sub-activities, including genetic modification, biosynthesis, cultivation or production of compounds of naturally occurring materials.[23] One or more of these specific acts of utilization could be set as the trigger points for a benefit-sharing obligation for resources in the high seas. Choosing specific acts of utilization will establish a legally certain situation by being objectively verifiable (Tvedt and Young, 2007, pp. 66–8). What is retained here is that utilization can be categorized by stage of development from collection to product development (Tvedt and Young, 2007, p. 67). If the intention for a high seas benefit-sharing mechanism is to leave academic research untouched, such actions could be associated with commercial use. Whenever triggering action is discussed, the granting of a patent is often mentioned. This action could provide a clear point of demarcation for commercialization. However, historically non-commercial actors, such as universities, are increasingly seeking patent protection. Concerning monetary benefits, a granted patent does not automatically indicate whether any economic benefit has accrued to the party, because the entry into market of an invention may lie years ahead (Salpin and Germani, 2007, p. 16). If obligations were triggered before revenue is gained, bioprospectors and industry would have to factor in yet another cost to the already risky investment. It could be perceived as taxing risk-taking. Its effect on willingness to

explore and innovate is hard to assess, but some would doubtlessly see the trigger as a disincentive to innovation.

A related option may prove better able to spur innovation: the granting of a patent could trigger a suspended obligation. "Suspended obligation" implies that an action in the present establishes an obligation in the future. This suspended obligation would then be triggered pending the realization of certain commercial successes occurring at a later stage. Such a suspended obligation would not impede innovation, but may be effective in providing funds for conservation and may contribute to the fair sharing.

An even later triggering moment could be set, for instance when the revenues from a commercial application exceed a particular sum or when the product has been on the market for a certain period of time. This would require patience in relation to some inventions. In terms of incentives, the sense of entitlement to the product will presumably grow as the moment of access recedes into the past, and benefit sharing will seem less and less natural in the eyes of the patent holder. Several years may pass from the sampling to the launching of a patented product. This is of particular relevance to the pharmaceutical industry where extensive trials are required. Uncertain but recurring indications estimate up to 15 years to develop a product in this sector.[24] The advantage of setting a particular gross net sum as a trigger is particularly appropriate with regard to the fair treatment of unsuccessful or semi-successful bioprospecting enterprises: one does not incur an obligation before benefits have arisen. In the absence of benefits, there seems to be little reason to adhere to a redistributive objective. On the other hand, it could arguably be taken as a penalty for success, and discourage the considerable investments needed for this particular form of innovation. In addition, targeting only the publicly successful ventures might incentivise companies to conceal when or where the actual benefits have been earned. This could be compensated to a certain extent by opting for forms of benefits other than monetary, such as the sharing of knowledge or information on samples.

A challenging question is how far away from the original sampled material the benefit-creating process can go before participation in a fund model becomes no longer necessary.[25] The question is what degree of similarity would be required for the obligation to be triggered. The answer lies somewhere between two extremes: where MGR have been a candidate in the research process, but not making their way into the final product; and the direct use of for instance a sampled micro-organism being used as a product in itself. This question is not particular to marine bioprospecting, it applies to all types of ABS, and has received surprisingly little attention.

Summing up, in order to promote innovation, the drafting of the trigger point for a mandatory solution requires legal predictability and must be set to an externally verifiable incident. Setting the trigger point into the future, will require more trust or a stronger system for control as the situation evolves with time.

If one assumes that possible obligations fall upon patentees with commercially successful inventions and only these, mandatory obligations would have to be surveyed to ensure compliance. Effective implementation of any such requirement could involve relying on the patent system. This would require resolving the controversial issue of disclosure of origin in patent applications.[26] Given the increasing tendency of universities to seek patent protection of their research results, a possibility is to target these users of biodiversity for particular benefit-sharing measures. Compulsory co-ownership of IPR would not be easily compatible with the fundamental exclusivity of the rights awarded to the inventor by a patent, so it would be difficult to establish a mandatory system. One could, however, invite universities to share and set up a practical system of ownership sharing for these patents with colleagues in disadvantaged states based on contracts. Participation of the wider scientific community could spur global innovation and not only meet the fairness objective. The drawback is that, if it is perceived as a burden on universities, they may become less attractive as partners to industry, and could in turn undermine efforts to promote innovation.

Sovereignty of the user country will, however, impede a change necessary to make the system functional, as requirements necessarily need to be transferred into domestic law to become binding. Not all user countries are likely to impose the same obligations on their domestic biotechnology.

For the sake of not impeding innovation, the literature recognizes the importance of an end point for the obligation (Drankier *et al*., 2012, p. 385; Young and Tvedt, 2009, pp. 23–4). An end point would increase economic predictability for a potential investor. On the other hand, one could argue that setting an end point does not necessarily affect the incentive to invent, because an obligation late in the life cycle of a product affects the innovation decision less than a monetary obligation early in the cycle. A bioprospector would probably not refrain from conducting a cruise and subsequent research because of monetary benefit sharing happening more than 20 years into the future. For conservation and sustainable use, there is no logic in defining an end point to the benefit-sharing obligation.

A further question that arises is that of who should be at the receiving end of monetary benefits. This is a challenge both for mandatory and voluntary models. There are many possible, worthy beneficiaries that could be envisaged for the conservation of biodiversity. Given the lack of investment in high seas conservation and protection of marine environments over the decades, recipients dedicated to the oceanic realm are likely candidates. To ensure an emphasis on conservation of the marine environment, a fund may transfer benefits to states, regional and global organizations or NGOs with specific conservation projects, *inter alia* marine protected areas. Funding could be awarded to research institutions for science projects relating to the loss of marine biodiversity or understanding marine life and diversity. In such a scenario, benefit sharing from bioprospecting would constitute a payment for the ecosystem services provided by the oceans to the whole of humanity, and be directed to preserving biodiversity, encouraging sustainable use, or fair sharing. It could also represent an incentive to conduct certain types of research rather than others. Theoretically, a high sea ABS system could even contribute to the *conservation* of mainland biodiversity and counter the practical shortcomings of benefit sharing in the CBD. To sum up, several political and technical constrains must be resolved for both mandatory and voluntary fund models. It is important, when discussing technical solutions, to be aware of which objectives are considered most important.

In the following, we ask whether certain forms of non-monetary options for high seas ABS may meet the set criteria more easily.

Second Policy Option: Creating a Common Pool of Sampled MGR

One approach to non-monetary benefit sharing would be to establish a common pool of biological material retrieved from the high seas (Greiber, 2011, pp. 36, 46–7). We will in this section explore how such an option could be conceived.

A common pool option draws on an open source approach, developed in the world of computer programming and software.[27] It shares some of the emerging ideas concerning a common pooling of biotechnological research and development (Tvedt, 2013),[28] along with the existing regime in the high seas. Non-monetary benefits could well hold a value that could lead to creation of economic values. They are regularly regrouped in a CBD-NP setting to include *inter alia* sharing of research results or samples, cooperation in scientific research and admittance to *ex situ* facilities or information databases.[29] Thus one non-monetary obligation could be to deposit a sample or a certain quantity of biological material in a common *ex situ* collection. Such an obligation would find a great advantage in not needing to differentiate between academic and commercially oriented cruises, as samples to a collection could be provided equally by any of them.

Biological resources *in situ* in the high seas seem to be common pooled resources, as the freedom of the high seas applies.[30] The general idea we explore here is to deposit duplicate samples retrieved from the high seas in a public trust *ex situ* collection to be made available to others in a non-exclusive or partially

exclusive manner. The basic idea behind this option is to spur innovation by making the material available for research and development for a greater scientific and perhaps also commercial audience than those with the financial resources to bioprospect in the high seas. Such a common pool collection model for samples from the high seas would entail a continuum of marine resources being open to all. Without such a common pool, collected biological material would often be held in private collections. Third party or public access would constitute a type of benefit sharing and thus meet the fairness criterion. This solution corresponds to the needs of the scientific community and users without the financial muscles to go on cruises in the high seas (Greiber, 2011, p. 36). Therefore, it holds promise to promote innovation amongst a greater grouping of inventors. The objective of *ex situ* conservation of marine resources will be fully met for this proposal.

For this common pool benefit-sharing option, the relevant trigger point could be the activity of collecting samples, or at a later stage when the material has been processed or subject to research. It is possible also to imagine later triggers, but if the benefit sharing requires samples-deposit, the same negative aspects as for monetary sharing do not appear.

A common pool of genetic resources raises several challenges both regarding *the pool* and *the commonness* of the resources. Five legal and practical issues have been identified as important to the management of collections (Tvedt and Schei, 2009): defining the material or information included in the pool; regulate the legal position of the depositor; the management of the pool itself; the legal position of the user of material taken out of the pool and finally questions regarding ownership of the collection itself. These issues all need to be discussed if any such pool is to be a realistic option.

A common pool can contain either biological samples or information about such samples. If a common pool is to consist of samples, bioprospectors can be asked to deposit duplicate samples. These can be samples at different stages of being processed: from living samples in an aquarium-style collection to highly prepared laboratory samples of biological material. An aquarium would be the best option from a conservation perspective as species threatened by extinction could be saved *ex situ*. This would also be the most challenging option for the collectors, as keeping the specimen alive would require a lot of the collection itself and of on-board storage facilities until the specimen can be deposited. There are practical challenges to *ex situ* live collections too, as not all species can reproduce viable populations in captivity. It would therefore be worth exploring alternative methods of preparing and storing the samples at a later stage.

A common pool can be composed of information of any kind, such as *in silico*[31] processed data; sequencing data relating to the biological material; or research-derived knowledge. One option requiring a minimum of management could be achieved by way of a clearing-house mechanism, where information on the activity rather than the content of the findings is shared. Available sequencing data as a form of benefit sharing may disseminate knowledge fairly and irrespectively of where the recipients are located, and would be based on well-known methods. The advantages in terms of conserving biodiversity could, however, be more indirect than in the case indicated above concerning the depositing of material. In patent terms, any collection of samples or information databank can be used as prior art and hinder novelty or inventiveness. Therefore, how material or information is made available to the public through such a deposit system need to be finetuned with respect to any later patent applications concerning invention based thereon.

The second area in need of clarification concerns the conditions under which material is brought into the pool. The politically most challenging option would be to make it mandatory to share samples with the collections, as this would require global consensus amongst countries. A voluntary option would not put the same strain on researchers and industry, but would nevertheless require positive incentives to encourage sharing, for instance by allowing favourable access to the other accessions in the pool, or even benefits from discoveries or inventions that result from a deposit. A voluntary mechanism could also invite

parties to deposit material held in private collections and from others in addition to research vessels, such as mining operators or offshore drilling companies when they find or take out biological samples. By including material from sources other than bioprospecting, activities with potentially damaging environmental repercussions[32] could be contributing to the *ex situ* conservation of some of the biodiversity they put at risk.

All cases raise a fundamental question regarding the relationship between the collection and the depositing party. This relationship is particularly relevant if the depositor shall seek patent protection, as sharing might be postponed until after the patent application has been filed. This can imply a considerably delay, as time might be needed before a patentable invention is ready. There are three main alternatives: samples are held in trust on behalf of the depositor; samples are given without restriction and samples are pooled under certain specific conditions. In the former case, where the sample is held in trust, the collection holds the material, but its disposal must be cleared with the depositor. The depositor maintains full rights to the material as nothing is yet shared, but the material will be conserved *ex situ*. This option would, however, not spur innovation by others, but could provide conservation and to a greater extent take into consideration the needs of the depositor. On the other side of this scale, the depositor leaves the material to the common pool, but retains no rights to it. In this situation, the depositor retains the right to the sample that he keeps, but makes the duplicate sample openly available to the global commons, with sharing set at maximum. This option would meet the conservation criterion, spur innovation and promote sustainable use. In the intermediate situation, the material could be pooled under any type of contractual restriction from the depositor. In these cases, different formulas for setting conditions securing the incentive to innovate by the depositor are conceivable. One could be to prohibit sharing of the samples in the collection before a certain date or before the depositor has granted permission.

Any middleground option leaves flexibility to adjust the legal situation for individual bioprospectors in contracts. This is particularly relevant if the depositor is intending to apply for a patent to the material or an invention based on it. Should the depositor seek a patent, the conditions attached to the sample in question would need to sustain the maintenance of novelty and inventiveness criteria by keeping the sample undisclosed for the necessary time.[33]

This is closely related to the question of when material or information shall be shared with the collection. The main alternatives would be immediately following the collecting activity, or at any subsequent point of time in the process. If the system is mandatory, the trigger point needs to be specified; if the system were voluntary, there would be no formal need to specify the point of time beforehand. For a voluntary system, leaving flexibility in a middleground contractual solution seems most viable in order not to deter innovation.

The third issue that would have to be addressed in the case of both sample deposits and sequencing deposit solutions is the further management of the collections. Here, principles of sound management could be drawn from the practices of other collections.

It will be imperative to define the conditions on which others can remove the material in the collection for use. This is crucial of course because the whole idea of the system is to make accessions available to a larger audience of users. Conditions for use would need to be elaborated in some detail, and this could also be done by studying the standard agreements used by other collections. The rights of others to apply for patent protection must be specified. Other users need to know the conditions on which they invest in research on these samples. Ideally, these rules need to be made clearer than is the case for the rules regulating the relationship to patent law in the Standard Material Transfer Agreement (SMTA) of the ITPGRFA (Medaglia *et al*., 2013, pp. 43–7). Finally, questions of ownership to the collections as such and coverage of their maintenance cost, will need to be resolved before any collection can embark on the task of becoming the *ex situ* common pool of MGRs and information from ABNJ.

From a practical point of view, the institutional set-up needs to include public access collections. This is a method known from the plant sector where the International Agricultural Research Centres (IARCs) of

the Consultative Group on International Agricultural Research (CGIAR) collect and hold raw materials and plant genetic resources. These collections are crucial for the conservation of plant genetic resources,[34] and have played an important role in spurring innovation during the Green Revolution in the plant sector (Dano, 2007, pp. 3–6). Transferring this option to marine bioprospecting purposes could promote *ex situ* conservation of biodiversity.[35] For material deposits to reach the intended objective of fairness, a decentralized deposit system may be more efficient than a centralized option. An alternative to building collections from scratch would be to designate existing collections or research centres as repositories for these samples. Again, the functioning of CGIAR centres can serve as an example. In these institutional set-ups, the *ex situ* common pool is associated with capacity building initiatives and plant breeding for new varieties, if the collections are combined with research units.

Summing up, we believe that a common pool model holds greater promise to spur innovation than the fund model. Clearly, a system for ex situ conservation will generate more sustainable use and indeed conserve the resources. Whether a common pool model is more apt than a fund to promote fairness depends on how the both of them are construed.

Institutional Options

Traditionally, the concept of ABS belongs to the realm of areas under national jurisdiction.[36] Merging this concept with the regime of the high seas requires finding an apt institutional anchorage. This is a challenge that will have to be addressed by stakeholders advocating a change to the *status quo*. In this section, we examine some of the institutional alternatives that arise.

No agency currently has a mandate that would allow imposing mandatory bioprospecting regulation for ABNJ. Whereas resources under national jurisdiction may be accessed through a contract or a bilateral agreement, access to biological material in the ABNJ is not subject to any contractual counterpart. Benefit-sharing arrangements outside a system of international policies would have to take the form of self-imposed obligations through flag state jurisdiction. Ships are subject to the exclusive jurisdiction of the state under whose flag they sail.[37] Thus, when the minimum requirements of the law of the sea are met, states are free to regulate the conditions of access to biological material for their nationals. One possible option could be to make bioprospecting performed by nationals dependent on permits, the terms of which could require bioprospectors to share benefits. This would mean that undertaking obligations would be voluntary in international law.

From a state perspective, there are important political disincentives to enacting such domestic regulation. Principally, states have little, if any, incentive to place economic or practical burdens on their nationals when other states do not, as this would place national research institutions or industry in a position of competitive disadvantage in the international market. Furthermore, were states to enact such regulations, it could create a problem of flag-state shopping, at least for the private institutions conducting bioprospecting: private institutions would have an incentive to relocate to states without such measures and sail under the flag of that state.[38] The challenge to such an approach is even greater if no other states, or only a few, were to enact legislation: the burden of being a Good Samaritan is even heavier to carry alone. No such domestic legislation is known to have been enacted (Leary, 2009, p. 363).

An initial step would be to agree upon the aptness of a multilateral approach. For such multilateral approaches, it could be fruitful to envisage the resources as common pool resources, possibly with attached obligations (Tvedt, 2013). Some form of institutional entity or agency would be required to be in charge of, or associated with, a multilateral approach. The question is what sort of entity.

A possible institutional avenue is that of a regional approach to high seas ABS. Regional agreements that also cover ocean ABNJ are important in safeguarding the environment and biodiversity beyond the Exclusive Economic Zone.[39] Regional fisheries management organizations or frameworks like the

OSPAR Convention[40] may serve as examples. Regional agreements present certain characteristics that should be noted here. First of all, vast parts of the high seas are not covered by regional agreements. Placing ABS obligations on specific regions may discourage bioprospecting in those areas and thus not spur innovation. Second, it could also increase bioprospecting pressure on the areas with the least developed management systems, as access would probably be less regulated. And finally, there is less justification for monetary ABS as a means for achieving fairness in a regional context than in a global one, as national wealth is often more evenly distributed amongst parties to a regional agreement than they are at the global level. However, if ABS is seen as non-monetary and the benefits shared are scientific information or easier access to the knowledge that bioprospecting leads to, regional forums present with the advantages of existing structures and experience that can be beneficial to conservation and sustainable use, provided regional organizations are strengthened and a functioning distribution of scientific knowledge can be set up.

Another regulatory option could be for an international organization with responsibility for the end product to have a stake, for example, marine bioprospecting with a view to creating a pharmaceutical product could be regulated by the World Health Organization; food or agriculture could be regulated by the Food and Agriculture Organization. Such a sector-based approach, assessed from the perspective of the user, would have certain drawbacks. The sector within which an invention finds its use can be arbitrary and overlap others. Legal obligations will not be known until a later stage of the bioprospecting process. As predictability is an important factor for investing in bioprospecting, a sectoral approach could induce disincentives to innovate in areas where there is a sector-specific organization hoping to receive the benefits. The distribution of these disincentives is also likely to be uneven. For instance, if an active compound is identified and a commercial application is found in a sector with benefit-sharing obligations, it could be tempting not to invest further in product development in that sector. In this scenario, it would be better for the industry to explore whether the compound might not have an application in another sector that is not regulated by benefit-sharing obligations. This argument would not be valid if ABS was seen by the industry as positively business-friendly, or if all sectors were regulated. Both scenarios currently seem rather unlikely in their fullest extent. Other difficult questions would arise, such as what should be considered a sector, whether all sectors should be regulated, and whether it is rational to entrust a number of institutions with similar work. To sum up, a sectoral solution may prove contrary to the objective of spurring innovation. Nor is a sectoral approach on the table in the on-going discussions.

Another possible institutional haven for ABS policies on biological material in the high seas could be that of the CBD. It would involve entrusting some sort of institutional body, existing or to be created, with a role in connection with a COP decision under the CBD, an MOP decision under the NP, guidelines, or a new protocol.[41] With a view to conserving biodiversity and promoting sustainable use, this institutional option has certain advantages. Conservation and sustainable use of biodiversity in ABNJ are recognized objectives under the Convention: contracting parties have a general obligation to cooperate "in respect of areas beyond national jurisdiction" for the conservation and sustainable use of biodiversity.[42] Since 1992, the bodies of the CBD have grown increasingly proficient in this area. Benefit sharing could also build on ideas set forth in NP article 10 on a possible multilateral benefit-sharing mechanism for utilization of genetic resources in "transboundary situations" and situations where "it is not possible to grant or obtain prior informed consent". Here, parties to the Protocol could conceivably negotiate a global multilateral benefit-sharing mechanism that addresses high seas genetic material. That said, any agreement reached in this forum would in all likelihood be without the participation of the biggest biotech state, the United States.[43] The United States is also not party to UNCLOS, which decreases the relative value of this argument. Of greater importance is the lack of institutional roots in the CBD for high seas governance that go beyond the general principle of cooperation found in article 5 and the possibilities awarded by flag state jurisdiction through article 4. Legally, nothing stands in the way of taking the CBD as a starting point for

high seas ABS as long as the policies are in conformity with the law of the sea.[44] All the same, it might be perceived as presenting logical, or almost methodological, impediments. It may contradict the perception of UNCLOS as "the legal framework within which all activities in the ocean and seas must be carried out".[45] As noted by Greiber, joining a CBD-based global benefit-sharing mechanism could be interpreted as forum choice, and subsequently disconnect UNCLOS from ABS related to MGRs in ABNJ (Greiber, 2011, p. 34). This latter point could be detrimental to the potential and role of UNCLOS to protect the marine environment from all harmful human activity, and thus run counter to the objective of conservation and sustainable use.

It might be more fruitful to apply the CBD concept of benefit sharing to the "Constitution for the oceans" and an UNCLOS framework. An institutional path starting from an UNCLOS offset could ensure greater uniformity and integration with existing rights and obligations. It could also prove beneficial to conservation and sustainable use of biodiversity if synergy effects are attained from future purely environmental regulation of the high seas, such as marine protected areas. There is also a potential for synergies between future UNCLOS-related regulation and the global multilateral benefit-sharing mechanism envisaged in NP article 10. The provision has a wider scope of application than the high seas; it refers to utilization in "transboundary situations" and where "it is not possible to grant or to obtain prior informed consent". The idea behind NP article 10 was to bring genetic resources outside the scope of national sovereignty, sometimes referred to as "orphan genetic resources", under an ABS scheme (Tvedt, 2011, p. 15). The idea of closing access gaps or vesting a body with the competence to regulate a future mechanism under article 10 would have consequences for the question of sharing the benefits from bioprospecting in ABNJ.

As stated above, the views expressed by delegates to the Ad hoc Open-Ended Working Group, and echoed at the Rio + 20 summit, on the possibility of a new implementing agreement to UNCLOS has given new momentum to the question of oceanic governance.[46]An implementing agreement to UNCLOS holds great promise, such as the potential to take into account the inadequacies of the current law of the sea and adopt holistic and modern environmental governance of the high seas. Concerning bioprospecting, the potential is twofold: firstly, it would be an opportunity to address the problems encountered by deep sea bioprospecting activities, as to the legal status of biological material of the Area.[47] This legal clarity could in turn encourage research and innovation. Secondly, a new implementing agreement could provide an opportunity to render more effective what can be seen as existing benefit-sharing provisions under UNCLOS, such as technology transfer obligations.[48] It could become a means of promoting fairness in the exploitation of high seas biological material. It should be noted that an ABS regime, resembling that of the CBD, is a potential, though far from self-evident, ingredient in such an implementing agreement. The diversity of oceanic life faces a variety of great and imminent threats. A possible scenario is that even its most ardent proponents would drop the controversial issue of benefit sharing in order to solve other issues, considered to be more urgent. These are considerations that are closely related to the discussions on modalities of ABS options. In the context of an UNCLOS-associated process, the structure and size of an ABS entity would depend on how states perceive benefit sharing. If benefit sharing is viewed as the exchange of scientific knowledge, thus providing one form of fairness, a secretariat with the responsibility for administering an Internet platform may suffice.[49] The current online bioprospecting information resource maintained by the United Nations University may serve as an example here.[50] A modest institutional option could also be a clearing-house mechanism that receives notification of scientific research and ensures the further distribution of data (Matz-Lück, 2010, p. 69). If an ABS-system resembling that outlined in NP article 10 were envisaged, a larger structure could be required. As pointed out by Matz-Lück, full resource management, including scientific experts, compliance control and decision-making bodies, would require a permanent institution, and the question of legal personality would also have to be addressed (Matz-Lück, 2010, p. 68).

A candidate for the position of institutional umbrella for ABNJ ABS exists already within UNCLOS. The International Seabed Authority (ISA), located in Jamaica, is in charge of administering the mineral resources of the Area in accordance with principles set forth in Part XI. The legal status of seabed mineral resources as common heritage of mankind and the provisions on technology transfer can be seen as founded on objectives that reflect the "fairness" sought by ABS proponents. Additionally, the fact that the ISA is an already existing institution is an important argument for the ISA assuming the role of managing a future ABS regime for the high seas. It is most commonly evoked in relation to an expansion of its mandate to include the biological resources of the Area. But it could also be associated with bioprospecting in the water column above. As noted in an EU working paper, the ISA may also be put in charge of managing a *sui generis* system, thus avoiding fragmentation of international agencies, while benefiting from existing structures and expertise and increasing the activities of an underused body.[51] Politically, however, this scenario may prove exceedingly hard to realise, given the difficulties that arose relating to the resources of the Area when UNCLOS was adopted. Another alternative for ABS proponents would be to advocate for the creation of a separate institution with less ideologically controversial baggage. Whether this strategy is fair, is another question. Developing countries can argue that history so far has cheated them of the fervently fought for benefits of the common heritage regime, as mineral prospecting has yet to prove commercially lucrative.[52] Amending or interpreting the regime of the Area to apply to biological material on the ocean floor, seabed and the water column above could in that regard be a fair redress of fate's irony. Nevertheless, this scenario remains politically difficult and could inhibit progress on the issue.

A less controversial platform for high seas ABS could also be created in the future. Two ideas for global institutions could be explored: the one of creating a World Environmental Organisation (WEO) or the empowerment of a global genetic resource ombudsman. The idea of a WEO was launched before Rio + 20, but did not become a reality there. Yet increased interest in global marine governance could perhaps be one of the developments that could make this institutional change regain global interest.

The idea of a genetic resource ombudsman has been tabled on a couple of occasions at ABS negotiations under the CBD. The idea here is to create an independent advisory and surveillance system to monitor potential breaches of ABS obligations. If no agreement can be reached to establish an authority in connection with the UNCLOS, the ombudsman system would be worth exploring in greater detail.

The task of finding the appropriate forum cannot be evaded. Whether the entity is built upon the CBD, UNCLOS or other instruments, its characteristics will as showed above depend on the rights and obligations proposed.

Concluding Remarks

It is far from easy either from a technical legal perspective or in terms of what is politically feasible to set up a regulatory environment for bioprospecting in the high seas. With a view to encouraging scientific research and innovation, a fund or a state-to-state approach with mandatory monetary benefit sharing can provide disincentives to innovate.

If no distinction is made between academic and commercial research, and obligations fall on both from the sampling moment, it could represent a step away from the current regime for scientific research as a freedom of the high seas under UNCLOS.[53] The compatibility of new regulations with the existing framework would depend on what obligation actually is placed on the bioprospectors.

The negotiations leading to the ITPGRFA and the NP show how sensitive the trigger point issue is. It is also probably the most crucial issue to resolve for an ABS system to become functional. Neither the definitions in NP article 2(c), nor the solutions in the ITPGRFA, are particularly well drafted if the objective is to establish legal basis for creating large revenues. If a system is meant to be mandatory, the

formulation of the trigger points is crucial because they must be made legally binding in national law to create obligations on the users. Noting the recent EU proposal for user country measures to meet NP obligations[54] and the non-membership to the CBD of the United States as a core biotech economy, there will likely be substantial political difficulties connected to specific mandatory trigger points also regarding marine bioprospecting.

Building on UNCLOS policy of making research available would be less threatening to the safeguarding of innovation. The idea of a common pool means strengthening UNCLOS objectives of disseminating research and technology. It too has drawbacks in limiting the exclusivity otherwise offered to bioprospectors, though the exclusivity offered by a patent would still be intact. Ironically, though, most of the challenges to innovation indicated above under this option come from patent law, which has as its primary justification the protection of investments and the promotion of innovation.

Compared to the monetary transfer scenario discussed above, this option has important advantages for the promotion of scientific innovation. It also provides a way of rendering operable the technology-transfer provisions of UNCLOS, and thus meet the objectives of the negotiators of the "Constitution for the oceans". Rendering what are initially *in situ* common pool resources *de facto* common pool resources in the wild, irrespective of economic capacities, could provide fairness and spur innovation.

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Notes

1. United Nations Convention on the Law of the Sea, 1833 UNTS 3, adopted on 10 December 1982.
2. Convention on Biological Diversity, 1760 UNTS 79, adopted on 5 June 1992, article 15.
3. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, adopted on 29 October 2010.
4. The Area is the "sea-bed and the ocean floor and the subsoil thereof beyond national jurisdiction". UNCLOS, article 1(1).
5. See for example, Glowka (1996, pp. 154–78), Oude Elferink (2007), Matz-Lück (2010) and Scovazzi (2010).
6. Established by resolution of the United Nations General Assembly, *Oceans and the Law of the Sea* (A/RES/59/24, 2004).
7. Ibid., paragraph 73(d).
8. See for example, Ad Hoc Open-Ended Informal Working Group, *Letter dated 15 May 2008 from the Co-Chairpersons of the Ad-Hoc Open-Ended Informal Working Group to Study Issues Relating to the Conservation*

of Marine Biological Diversity in Areas Beyond National Jurisdiction to the President of the General Assembly (A/63/79), paragraphs 6 and 10.

9. Ad Hoc Open-Ended Informal Working Group, *Letter Dated 8 June 2012 from the Co-Chairs of the Ad Hoc Open-ended Informal Working Group to the President of the General Assembly* (A/67/95, 2012), paragraphs 15–9.
10. International Treaty on Plant Genetic Resources for Food and Agriculture, 2400 UNTS 303, adopted on 3 November 2001.
11. Ad Hoc Open-Ended Informal Working Group, *Letter dated 15 May 2008 from the Co-Chairpersons of the Ad-Hoc Open-Ended Informal Working Group to Study Issues Relating to the Conservation of Marine Biological Diversity in Areas Beyond National Jurisdiction to the President of the General Assembly* (A/63/79), paragraph 38.
12. UNCSD, Report of the United Nations Conference on Sustainable Development (A/CONF.216/16, 2012), paragraph 162.
13. Ad Hoc Open-ended Informal Working Group, *Letter Dated 30 June 2011 from the Co-Chairs of the Ad Hoc Open-ended Informal Working Group to the President of the General Assembly* (A/66/119, 2011), paragraph 6.
14. On the effects of the economic downturn for biotechnology, see Giovannetti and Jaggi (2012, pp. 25–39).
15. CBD, article 2, paragraph 13.
16. *Ibid*., article 2, paragraph 8.
17. Its provisions apply in relation to each contracting party to areas within national jurisdiction and may only be extended to ABNJ as a result of flag state jurisdiction. See *ibid*., article 4(a) and (b).
18. See World Commission on Environment and Development, *Report of the World* Commission on Environment and Development: Our Common Future (Annex to document A/42/427, 1987), part IV, paragraph 1.
19. *Ibid*. See Sands (2003, p. 253).
20. See UNCLOS, preamble, paragraph 5. On the justice in using genetic resources, see Schroeder and Pogge (2009).
21. See COP4, *Adressing the Fair and Equitable Sharing of the Benefits Arising out of Genetic Resources: Options for Assistance to Developing Country Parties to the Convention on Biological Diversity* (UNEP/CBD/COP4/22, 1998), p. 3. This link has been contested, see Simpson (1997).
22. For a discussion of these challenges, see Tvedt and Young (2007, pp. 59–96).
23. Ad Hoc Open-ended Working Group on Access and Benefit-sharing, *Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Defintions and Sectoral Approaches* (UNEP/CBD/WG-ABS/7/2, 2–9 April 2009).
24. See for example, Smagadi (2009, p. 29).
25. This thought draws inspiration from Young and Tvedt (2009, p. 24).
26. See generally Hoare and Tarasofsky (2007); Tvedt (2006, p. 204).
27. On the development of the open source movement, see for example, Mandrusiak (2010, pp. 313–6).
28. See for example, Kamau and Winter (2013).
29. See NP, annex, article 1(2).
30. See for example, Broggiato (2011, p. 36); also Leary (2009, p. 362). Both put particular emphasis on sampling in the deep seas of areas beyond national jurisdiction.
31. That is "describing biological processes or experiments that are simulated by a computer program", Oxford University Press (2012).
32. On the environmental impacts of seabed mining and fossil fuel extraction compared to bioprospecting, see Ramirez-Llodra *et al*. (2011, pp. 11–5).
33. Agreement on Trade-Related Aspects of Intellectual Property Rights, adopted on 15 April 1994, article 27(1). There are different understandings of the "novelty" requirement, ranging from an absolute novelty requirement to a local novelty requirement, see Grubb (1999, pp. 54–8).
34. On the history and functioning of the CGIAR, see Fowler and Mooney (1990, pp. 150–1); FAO (FAO, 1997, p. 253); Louafi (2013).

35. Potentially, but controversially, it could be used as a means reintroduce endangered species into the wild. Given the vastness of the ocean, how useful such reintroduction is would have to be evaluated along with the considerations of ecological impacts of reintroduction in general.
36. See CBD, article 15, which establishes that the authority to determine access to GR rests with national governments and is subject to their legislation, while obliging states to take measures to share benefits arising from the commercial utilisation of these GR. See also article 4 concerning the jurisdictional scope of the convention.
37. UNCLOS, article 92(1).
38. Pursuant to UNCLOS article 91 there must nonetheless be a "genuine link between the State and the ship".
39. For an introduction to the most important regional treaties and their importance in protecting marine ecosystems, see Warner (2009, pp. 173–205).
40. Convention for the Protection of the Marine Environment of the North-East Atlantic, 2354 UNTS 67, adopted on 22 September 1992.
41. See Greiber (2011, p. 34). He argues against CBD-associated organs hosting a global multilateral benefit-sharing mechanism.
42. CBD, article 5.
43. The United States signed the CBD in 1993, but never ratified it. UNCLOS and the Implementation Agreement Relating to Part XI were sent to the American Senate in 1994, where ratification was rejected. For the comparative dominance of the United States in biotechnology, see Giovannetti *et al*. (2011).
44. CBD, article 22(2) provides that parties shall implement the convention "with respect to the marine environment consistently with […] the law of the sea".
45. United Nations General Assembly, *Oceans and the Law of the Sea* (A/RES/66/77, 2011), preamble, paragraph 4.
46. See generally Hart (2008). See also Chiarolla *et al*. (2012).
47. On the long-standing, unresolved paradoxes of the legal status of MGR in the Area in relation to the Common Heritage of Mankind, see Glowka (1996, pp. 154–78), Leary (2007), Oude Elferink (2007), Leary (2012, pp. 435–48).
48. UNCLOS, Part XIV. This part of the Convention is considered by some parties to be the Part with the gravest implementation gaps. See Ad Hoc Open-ended Informal Working Group, *Letter Dated 30 June 2011 from the Co-Chairs of the Ad Hoc Open-ended Informal Working Group to the President of the General Assembly* (A/66/119, 2011), paragraph 36.
49. See Matz-Lück (2010, p. 68). Her institutional proposals concern management of the living resources in the Area.
50. United Nations University (2012). The database publishes known information on research and commercialised products arising from bioprospecting in the four categories of Antarctic, Pacific, Marine and Arctic bioprospecting.
51. Council of the European Union, *Reflections on the Management of Genetic Resources in Areas Beyond National Jurisdiction* (*Background paper 12*) (11510/06 ADD 12, 2006), p. 9. See also Matz-Lück (2010, pp. 72–3), who favours this option for biological resources in the Area, but recognises its unlikelihood.
52. De la Fayette considers that if delegates negotiating UNCLOS had known about the economic potential of genetic resources when the Convention was negotiated, surely they would have included them in Part XI. De la Fayette (2010, p. 77).
53. UNCLOS, Part XIII.
54. The European Commission, *Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union* (COM (2012) 567 Final, 2012).

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